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## DECLARATION OF ANNETTE S. PARENT, Ph.D.

### OPPOSITION BY PROTEIN DESIGN LABS, INC., TO EUROPEAN PATENT 0 125 023 OF GENENTECH, INC.

I, Annette S. Parent, Ph.D. declare and state as follows:

1. I am an attorney at law and a member of the California State Bar. I have been assigned to investigate the public availability of U.S. government research grants funded by the National Institutes of Health (hereinafter "NIH"). This declaration addresses the issue of public notification that a specific grant application has been funded.

2. During my investigation I called the NIH and was referred to Leo F. Buscher, Chief of the Grants Administration Branch of the Office of Administrative Management for the National Cancer Institute (hereinafter "NCI"), NIH. I asked him to what extent in 1983 the public was notified that a grant such as the Herzenberg grant was funded. He told me that the pertinent information was provided in a book that he wrote and offered to send me a copy.

3. On Thursday, March 6, 1997 I received the book written by Leo F. Buscher entitled *Everything You Wanted to Know about the NCI Grants Process . . .*, U.S. Department of Health and Human Services, NIH Publication No. 95-1222 (1994). Pertinent portions of the book that address the NIH procedure for public notification that a specific grant has been funded are attached as Exhibit A. In particular, on page 56 the book states:

Copies of the [grant] award notice are mailed to the grantee institution, the grantee business office, and the principal investigator. Internal copies are distributed to the appropriate NIH and NCI offices. . . . For all new and competing continuation awards, Congress must be alerted at least 72 hours before the issuance of the [grant] award so the appropriate representatives have the opportunity to notify their constituents.

Therefore, under this NIH procedure, public notification that the Herzenberg grant application had been funded would have been immediately disseminated to the principal investigator (Dr.

Leonard Herzenberg), his research institution (Stanford University), the Stanford University business office, the NIH, the NCI, and the appropriate congressional representative.

4. Mr. Buscher's book states that NIH procedures are based on grant application type. Pertinent portions of the book that describe the grant application types and how they are identified are attached as Exhibit A. In particular, on pages 93-94 the book defines the nine grant application types and lists the codes used to identify them. For example, code number "2" identifies a competing continuation grant application, and code number "5" identifies a noncompeting continuation grant application. On page 26 the book provides an example of a grant application number and what it signifies. For example, the grant application number incorporates the code for application type at the beginning of the grant application number. Therefore, according to the example on page 26 and the codes on page 93 of the Buscher book, the Herzenberg grant number 2 R01 CA04681-24 identifies the grant as a competing continuation grant application in its 24th year of requested support.

5. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: 3/26/97

By: Annette S. Parent, Ph.D.  
Annette S. Parent, Ph.D.

The National Cancer Institute Presents...

**Everything You Wanted  
to Know About the  
NCI  
GRANTS  
PROCESS...**

**But...  
Were Afraid  
to Ask**

**NATIONAL INSTITUTES OF HEALTH  
National Cancer Institute**

National Cancer Institute

**GRANTS PROCESS  
AND  
ADMINISTRATION**

LEO F. BUSCHER JR.  
GRANTS MANAGEMENT OFFICER  
NATIONAL CANCER INSTITUTE

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

NIH Publication No. 95-1222

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## Preface

The purpose of this publication is to describe, in a general way, how a grant is awarded and administered. Although the discussion relates to the National Cancer Institute (NCI), the grants process is similar in the other National Institutes of Health (NIH) awarding components. We hope that this information will provide a starting point in understanding the overall award process.

The organization of this publication represents a concise progression through the subject of the NCI grants process and administration. Thus:

- Part I, An Overview, provides an introduction to how we in the Grants Administration Branch view our role in this very important collaborative venture, a snapshot of the NCI as an organization, and a brief perspective of the legal underpinnings for grants.
- Part II, Process and Administration, charts the path of a grant application from development, receipt, and assignment, through the peer review process, NCI funding determinations, award negotiation and issuance, and, finally, postaward administration.
- Part III, titled References and Resources, provides a listing of materials and organizations to help in illuminating various nuances of the NCI grants process.

It is a pleasure to acknowledge the contributions of the entire staff of the Grants Administration Branch who through their efforts made this publication possible. I would also like to acknowledge the staff of NOVA Research Company for their excellent logistical support.

For those who seek additional knowledge or information concerning the subject matter in this publication, the staff of the Grants Administration Branch are pleased to answer any inquiries. Additionally, we welcome your suggestions to improve this document.



Leo F. Buscher Jr.  
Grants Management Officer  
National Cancer Institute  
(301) 496-7753

Each new application received is assigned an identification number, checked for completeness, and duplicated. Copies of the application are forwarded to the appropriate Institute and IRG. The following is an example of a grant application identification number:

| Application Type | Activity Code | Administering Organization | Serial Number | Suffix Grant Year | Other |
|------------------|---------------|----------------------------|---------------|-------------------|-------|
| 1                | R01           | CA                         | 83723         | 01                | A1 S1 |

When an application is funded, this becomes the grant number.

There are nine grant application types that may be used to identify the stages in the life cycle of a grant. A description of these nine application types is provided under Part III, the "Application Types" section.

The above number identifies a new (Type 1) application for a traditional research project (R01) assigned to NCI (CA). The serial number, which is assigned sequentially by the Division of Research Grants, indicates that it is the 83,723rd application assigned to the NCI. The suffix (01) shows that this is the first year of requested support for this project. The next part of the suffix may be present to identify amendments and supplements.

The NCI also has referral officers. These individuals review and direct all NCI applications to the appropriate NCI program director. The program director follows the progress of his/her assigned applications through the review process. The NCI establishes an official file for each application and enters fiscal and scientific information into the NIH/NCI data systems.

### Principal Investigator

The principal investigator is designated by the grantee institution to direct the project being supported by the grant. PIs are responsible and accountable to grantee organizational officials for the proper conduct of the project. The PI accepts responsibility for the scientific conduct of the project and submission of progress reports by signing the grant

The Grants Management Officer certifies in signing the grant award that:

- The choice of the award mechanism is proper under applicable policy.
- The application on which the award is based was properly peer reviewed.
- The applicant institution is judged to have (or is expected to acquire) adequate business management capability to administer the grant and account for Federal funds.
- The award is being made under the terms and conditions specified for the particular program and is consistent with appropriate review recommendations.
- The award is consistent with governing legislation, regulations, and policies.
- All review and award actions are clearly documented in the official grant files.

The award amount is forwarded to the Division of Financial Management, NIH, where it is recorded as an obligation in the NIH official accounting records. Copies of the award notice are mailed to the grantee institution, the grantee business office, and the principal investigator. Internal copies are distributed to appropriate NIH and NCI offices.

### *Congressional Notification*

For all new and competing continuation awards, Congress must be alerted at least 72 hours before the issuance of the award so the appropriate representatives have the opportunity to notify their constituents. If the award exceeds \$1 million, the White House may also be informed. This requirement is fulfilled by forwarding a copy of the award notice to the Office of Congressional Liaison, DHHS.

## Application Types

There are nine grant application types that may be used to identify the stages in the life cycle of a grant. The grant type defines the procedures and specifies the documents required to process the grant award.

### Code

- 1 New—Original request for Public Health Service support of a particular project or activity.
- 2 Competing Continuation—Request for support to extend a project period that would otherwise expire for one or more additional budget periods. Competing continuation applications compete with other competing continuation, competing supplemental, and new applications for funds.
- 3 Supplement—Request for additional funds, either for the current operating year or for any future year previously recommended.
- 4 Extension—Request for additional time and/or funds beyond that previously recommended for MERIT (R37) applications. Type 4 MERIT applications compete for funds, but with a requirement only for National Advisory Council review.
- 5 Noncompeting Continuation—Request to award previously recommended support; does not compete for available funds.
- 6 Change of Institute (new)—Original request for support (Type 1) of a project or activity that has been transferred from one awarding organization to another (Fellowship and Training Programs only) before award.



- 7 **Change of Grantee**—Request for support of a project or activity to be transferred from one grantee institution to another.
- 8 **Change of Institute, Center, or Division**—Request to award previously recommended support (Type 5) of a project or activity that has been awarded from one awarding component to another.
- 9 **Change of Institute**—Request for continuing support of a project or activity that has been transferred from one awarding organization to another before the competing (Type 2) award.

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